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Designation of new food additives (3-Methyl-2-butanol, et. al.)

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:
On October 2, 2009, the Japanese Government announced the planned approval of new food additives, 3-Methyl-2-butanol and 5,6,7,8-Tetrahydroquinoxaline. The domestic comment period closed on October 16, 2009. MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject.

General Information:
The Japanese Ministry of Health Labour and Welfare (MHLW) announced the planned approval of new food additive, 3-Methyl-2-butanol and 5,6,7,8-Tetrahydroquinoxaline. The period for sending comments on these changes ended October 16, 2009. If you have comments it is best to send directly to MHLW as soon as possible; however MHLW will also notify these proposed changes to the

WTO/SPS committee, providing another chance for public comments to be submitted on this subject. Then after the closing of the WTO comment period, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

Further questions regarding these additives can be addressed to the Japanese Government in either Japanese or English.

Please send them directly to:

Standards and Evaluation Division,
Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
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Food Additive Regulations:
Designation of Food Additives

Purpose and background
The Ministry of Health, Labour and Welfare is going to newly designate two substances as authorized food additives.

Under Article 10 of the Food Sanitation Law, food additives can be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. When use standards or compositional specifications are established for food additives based on Article 11 of the law, those additives are not permitted to be used or marketed unless they meet these standards or specifications.

In response to a request from the Minister, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the authorization of the two substances 3-Methyl-2-butanol and 5,6,7,8-Tetrahydroquinoxaline. The subcommittee has concluded as follows.

Outline of conclusion
The Minister should designate 3-Methyl-2-butanol and 5,6,7,8-Tetrahydroquinoxaline, based on

Article 10 of the Food Sanitation Law, as food additives unlikely to harm human health and establish compositional specifications and other necessary standards for the substances, based on Article 11 of the law (see Attachments 2-1 and 2-2).

Additional Information

Progress in the designation procedure of food additives that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan (Attachment 2-3)

Attachment 2-1

3-Methyl-2-butanol

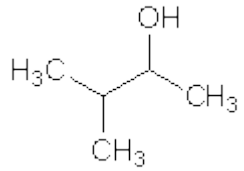
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 3-Methyl-2-butanol

Structural formula



Molecular formula $C_5H_{12}O$

Mol. Weight 88.15

Chemical name, CAS number 3-Methylbutan-2-ol [598-75-4]

Content 3-Methyl-2-butanol contains not less than 98.0% of 3-methyl-2-butanol ($C_5H_{12}O$).

Description 3-Methyl-2-butanol occurs as a colorless, transparent liquid having a characteristic odor.

Identification Determine the absorption spectrum of 3-Methyl-2-butanol, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

Purity

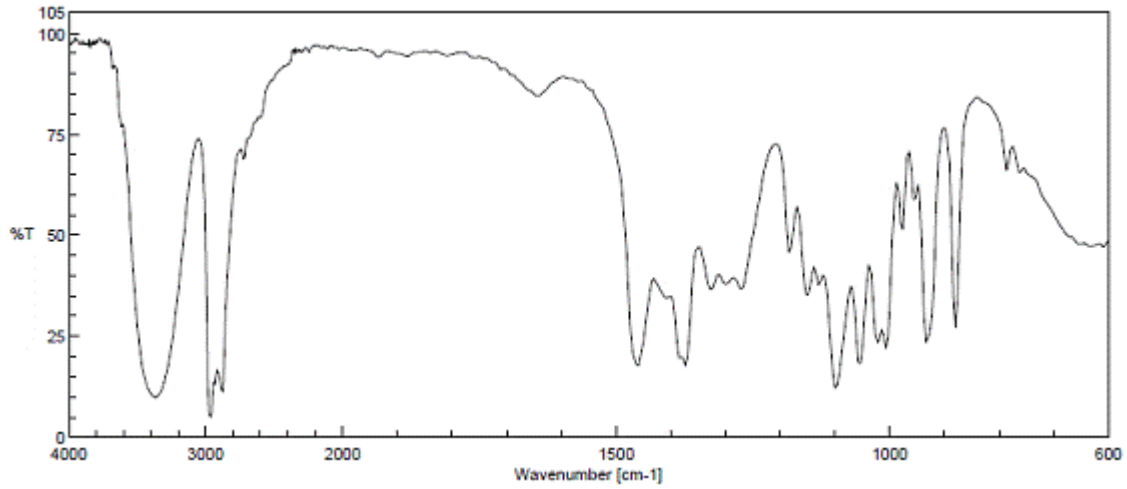
(1) Refractive index n_D^{20} : 1.406–1.412.

(2) Specific gravity d_{25}^{25}: 0.815–0.821.

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).

Reference Spectrum

3-Methyl-2-butanol



Attachment 2-2

5,6,7,8-Tetrahydroquinoxaline

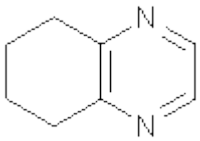
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 5,6,7,8-Tetrahydroquinoxaline

Structural formula



Molecular formula $C_8H_{10}N_2$

Mol. Weight 134.18

Chemical name, CAS number 5,6,7,8-Tetrahydroquinoxaline [34413-35-9]

Content 5,6,7,8-Tetrahydroquinoxaline contains not less than 98.0% of 5,6,7,8-tetrahydroquinoxaline ($C_8H_{10}N_2$).

Description 5,6,7,8-Tetrahydroquinoxaline occurs as a colorless to light yellow liquid, having a characteristic odor.

Identification Determine the absorption spectrum of 5,6,7,8-Tetrahydroquinoxaline, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

Purity

(1) Refractive index n_D^{20} : 1.540–1.550.

(2) Specific gravity 1.078–1.088.

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay

under the Flavor Substance Tests. Use operating conditions (1).

Reference Spectrum

5,6,7,8-Tetrahydroquinoxaline